REMARKS/ARGUMENTS

Claims 1, 3, 6 and 7 are pending in the application. Claim 1 has been amended. Applicant reserves the right to present any withdrawn or canceled subject matter in one or more continuation or divisional applications.

Objection under 35 U.S.C. §132

The Examiner has rejected the phrase "to a human patient in need thereof" as new matter. This rejection is traversed. Solely to promote prosecution, claim 1 has been amended to delete this phrase. Claim 1 is definite as amended. One skilled in the art would be well aware, based on the disclosure, that the claims and the application are directed to a method of treatment, e.g., of humans in need thereof. There is disclosure throughout the specification that a disease is treated using the compounds disclosed therein, and a range of diseases that can be treated are described. Based on the disclosure of the specification, the claims would be clear to one of ordinary skill in the art.

Rejections under 35 U.S.C. § 102(b) and §103

Claims 1, 3, 6 and 7 have been rejected under 35 U.S.C. § 102(b) as anticipated by, and under 35 U.S.C. § 103(a) as obvious over, U.S. Patent No. 5,212,158 to Vandai.

Vandai fails to disclose treatment of a postlesional neuronal disease due to cerebral infarction or traumatic impact characterized by nerve cell necrosis as recited in the amended claims. There is no suggestion from Vendai's disclosure of the methods defined by the claims.

Amnesia is not a specific disease, but instead is a symptom. Vandai describes compounds with nootropic activity. Vandai describes treatment of amnesia induced by the absorption of scopoloamine (see col. 3, lines 54-57). Vandai fails to disclose or suggest amnesia due to traumatic impact. See also col. 13, line 8 ("amnesia induced by scopolamine") and column 13, line 63 ("amnesia induced by diazepam").

Amnesia of traumatic origin is readily distinguishable from amnesia induced by a chemical substance, e.g. by computer tomography (CT), magnetic resonance imaging (MRI), sonography, or toxicological analysis of blood serum.

The present claims are directed to the treatment of a postlesional neuronal disease due to traumatic origin, and not to the treatment of amnesia induced by a chemical substance. The present claims are directed to a method wherein an effective amount of a compound of Formula I is administered to stimulate nerve growth to effect the claimed treatment, which is not suggested in the disclosure of Vandai.

Vandai does not disclose or suggest a mechanism of action of the compounds described therein that would indicate any suitability for use in postlesional diseases characterized by nerve cell necrosis, as recited in the claims. Vandai discloses the alleged *nootropic* effects of the described compounds.

Furthermore, the alleged disclosure of treatment of neurodegenerative diseases in Vandai does not anticipate or render obvious the amended claims to the treatment of postlesional diseases. The promotion of neurite growth – which is a prerequisite for the treatment of postlesional diseases of necrotic origin – does not belong to one of the possible mechanisms of action known from the literature, and has no connection whatsoever with the mechanism of action known for nootropics.

The usefulness of the claimed substances for treating postlesional neuronal diseases due to cerebral infarction or traumatic impact characterized by nerve cell necrosis is moreover non-obvious in view of Vandai. Applicants reiterate the comments in the previously filed Amendment that there are differences between a therapeutic treatment of neurodegenerative conditions such as for example Alzheimer's disease, and regenerative processes which are essential for the treatment of postlesional diseases of the nervous system due to cerebral infarction or traumatic impact characterized by nerve cell necrosis.

As noted in the previously filed Amendment, in the pertinent literature, a difference is drawn between a therapeutic treatment of neurodegenerative conditions, for which nootropics are used, such as for example Alzheimer's disease, and *regenerative* processes which are necessary for the treatment of postlesional diseases of the nervous system, as presently claimed (see Varon and Connor (1994) "Nerve Growth Effector in CNS Repair" in *Journal of Neurotrauma*, vol. 11, no. 5, Exhibit B, attached with Applicant's Amendment dated April 15, 2005).

This reference supports the contention that the nootropic or even anti-neurodegenerative effect of certain substances does not render their effect on regenerative processes obvious. The present application contains experimental data proving the neuro-regenerative effect of the compound Cinnamoyl-GFPNH$_2$, which supports the neuro-regenerative effect of the compounds recited in the claims. There is no suggestion in Vandai that the compounds recited in the amended claims are regenerative. There is therefore no suggestion in Vandai that these compounds could be used in a method of treatment of postlesional diseases characterized by necrotic cell death, as recited in the amended claims, which require such regeneration.

Vandai does not disclose or suggest the methods defined by the amended claims. None of the other references cited by the Examiner provide any additional teaching that would have suggested the claimed methods to one of ordinary skill in the art in the absence of hindsight. Therefore withdrawal of this rejection is respectfully requested.

Double Patenting Rejections

Claims 1, 3, 6 and 7 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-7 of U.S. Application No. 10/635,696. It is noted that prosecution of U.S. Application No. 10/645,696 is not being continued, and therefore it is submitted that this rejection is moot.

Conclusion

In view of the above arguments, withdrawal of the outstanding rejections is respectfully requested.

The Commissioner is authorized to charge any fees associated with this filing not attached hereto to Deposit Account 11-0980.

Respectfully submitted,

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